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# Enhancing our anti-diversion program

January 23, 2013

Dear ISF colleague,

The safety and security of our nation's pharmaceutical supply chain is a top priority for Cardinal Health and a responsibility we take very seriously. A safe and reliable drug supply is central to our customers' businesses and critical to the health and well-being of their patients. We believe that we must work together with our customers to ensure that they have an adequate supply of controlled substances to meet the legitimate needs of their patients while addressing the societal issue of prescription drug abuse.

Part of our efforts to continuously improve our anti-diversion program is an enhanced threshold-setting methodology. **We will begin using this new methodology on February 1, 2013.**

**Prescription count serves as the foundation**
A pharmacy that fills 1000 prescriptions per day requires more prescription drugs – and more controlled substances – than a pharmacy that fills 100 prescriptions per day. With this in mind, we use each customer's prescription count as the foundation of our threshold-setting methodology. For many customers we have limited visibility into the number of prescriptions they fill. In these situations, we calculate a prescription count based on the customer's purchases from us, accounting for pricing of generic and brand drugs. This ensures that the volume of controlled substances we distribute to a customer is justified by their prescription volume.

**The more data we have, the more accurate the prescription count will be**
Customers that do not buy all of their drug products from us, particularly those purchasing significant amounts from other distributors, may not be pleased with this calculation of prescription volume. This new method ensures that our distributions of controlled substances to our customers make sense based on our knowledge of each customer.

However, if Cardinal Health has visibility into a customer's prescription volume through one of our offerings (customers using Inventory Manager, Reimbursement Consulting Services, and certain customers using Reconciliation), we will give the customer **50 percent credit** for the prescription volume associated with purchases from other distributors.

For customers not using one of these offerings, we are offering a data feed option that will provide visibility into the customer's prescription dispensing volumes. The sign-up form for this option will be available in late January 2013. Using actual dispensing volume will allow us to establish more accurate prescription counts and thresholds for customers that purchase non-controlled prescription drugs from other sources. Please note if the dispensing data reveals that a customer is purchasing controlled substances from other sources, this may result in lower thresholds with us for those drugs.

**Thresholds are based on national statistics**
Our thresholds for controlled substances are based on national statistics from a variety of sources including the Drug Enforcement Administration. For example, national statistics indicate that on average 4.5 percent of the prescriptions filled by a retail pharmacy are for oxycodone and hydrocodone combined. This is consistent with the dispensing volume of our customers. The average prescription for oxycodone and hydrocodone is issued for approximately 80 dosage units. Naturally, there is significant variation in the quantity dispensed depending on whether a prescription is issued for an acute or chronic condition. However, from our perspective as a distributor, we expect most customers' orders to be within a reasonable range of national averages.

*Example of National Average: Retail pharmacies in the U.S. fill an average of 4,300 prescriptions a month. 4300 prescriptions * 4.5% * 80 dosage = 15,480 oxycodone and hydrocodone dosage units combined.*

DEFENDANT EXHIBIT
CAH-WV-00476

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Every order for controlled substances poses a risk of potential diversion, even orders that are very small. Therefore, all of us must be vigilant in identifying other signs of potential diversion such as filling prescriptions issued for patients who are travelling significant distances to obtain controlled substances, the presence of long lines of what appear to be healthy, young customers waiting to obtain narcotics, and groups of people arriving at the pharmacy together with similar prescriptions for controlled substances.

One of the recurring ordering patterns among pharmacies that have been recently shut down by the DEA is that certain drugs strengths of concern constitute the majority of the orders for that particular drug family. For example, in many cases oxycodone 15 and 30 milligram products when combined comprised the majority of the oxycodone ordered. In response to this, we have established separate thresholds within a drug family for certain drug products that are more susceptible to diversion and abuse. Currently, we have established separate thresholds for oxycodone 15 and 30 milligram immediate release products and hydrocodone 10 milligram products. Our implementation of these "sub-base code" thresholds could have a significant impact on those customers whose orders for oxycodone or hydrocodone are primarily comprised of drug strengths of concern.

**We recognize that not every pharmacy is the same**
We make allowances for variation in the practice of pharmacy based on a wide variety of factors. We recognize that a limited number of pharmacies have a legitimate need for controlled substances in amounts that exceed the national average. However, only in limited circumstances will we allow a pharmacy to order controlled substances in amounts that exceed the national average, adjusting for overall prescription volume. In those limited circumstances we apply the following objective criteria in evaluating the customer:

| Objective Criteria | National average | 95th percentile |
|---|---|---|
| 1. The percentage of oxycodone that is oxycodone15 and 30 milligram products | 22% | 68% |
| 2. The percentage of hydrocodone that is hydrocodone10 milligram products | 33% | 73% |
| 3. The percentage of alprazolam that is alprazolam 2 milligram product | 16% | 83% |
| 4. The percentage of prescription drug dosage units that is controlled substances | 21% | 45% |
| 5. The percentage of all prescriptions that is oxycodone and hydrocodone prescriptions | 4.5% | 14% |
| 6. The percentage of controlled substances units dispensed that is an ADD/ADHD drug (i.e., amphetamine and methylphenidate) | 7% | 21% |
| 7. The percentage of controlled substances units dispensed that is a benzodiazepine (e.g., alprazolam, diazepam, midazolam, etc...) | 20% | 38% |
| 8. The percentage of all prescription drug dosage units dispensed that is an opiate (e.g., hydrocodone, oxycodone, methadone, morphine, oxymorphone, etc...) | 13% | 34% |

Our scoring system uses the objective factors to calculate a customer's score and pass/fail rating. This pass/fail rating will determine whether or not, and to what extent, we set thresholds above the national average. **Customers whose objective scores approach or exceed the 95th percentile in one or more of these areas as well as customers with a high cumulative score for the eight factors will receive additional scrutiny and thresholds will be managed accordingly.**

We established these objective criteria to help identify those pharmacies whose ordering patterns are similar to pharmacies that have been the subject of adverse DEA actions. Again, in order for our assessment to be accurate, we need visibility to customers' dispensing volumes through one of our offerings mentioned earlier. Without that information, we will use the more conservative approach of basing the objective assessment on purchases from Cardinal Health.

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Reductions in thresholds are not a justification to purchase the same controlled substance drug family from another distributor. If a customer chooses to do this, we may further reduce the customer's threshold or refuse to sell some or all controlled substances to that customer. We take this approach because the DEA has stated that purchasing the same controlled substances from more than one source is a pattern displayed by pharmacies that dispense controlled substances for other than a legitimate medical purpose.

**We will not fill any order for a controlled substance that exceeds a threshold**
Because our thresholds are based on prescription volume, we will not fill any order for a controlled substance that exceeds a threshold unless the customer meets our criteria for increasing the threshold to a level that will permit the order to be released. When customers approach a threshold early in an accrual cycle, you will receive notice and have an opportunity to interact with both the customer and QRA's analytics team to better understand the circumstances around the orders so that we can determine whether the threshold is appropriately set.

Order(s) exceeding a threshold and not filled will be reported to DEA as suspicious in compliance the DEA regulation found at 21 C.F.R. §1301.74(b).

If a customer reaches a threshold in a drug family the customer will not receive any more of that drug family during the remainder of the customer's accrual cycle unless QRA determines that an increase in the customer's threshold is warranted. The process for determining whether a threshold increase is justified includes analyzing data against the objective criteria and may include the following: review of the dispensing practices of the pharmacy; the location of the pharmacy; the customer's business model; regional dispensing practices; and a site visit to the pharmacy.

We recognize that our pharmacy customers must sometimes make difficult decisions about whether prescriptions for controlled substances are issued for a legitimate medical purpose. The DEA's decisions to revoke the DEA registration of pharmacies indicate that a pharmacist cannot simply rely upon a prescriber's claim that a prescription is legitimate. Pharmacists must be alert to a variety of warning signs and must refuse to fill prescriptions if the pharmacist questions whether the prescription was issued for a legitimate medical purpose. You should encourage your customers to [ HYPERLINK "http://www.deadiversion.usdoj.gov/fed_regs/actions/2012/index.html" ] that are found on the DEA's website.

The enhancements to our anti-diversion program will help our customers and protect society. The new threshold-setting methodology is driven by analytics and objective data. Therefore, we are better able to communicate proactively with you and your customers to ensure that thresholds are properly established and that we understand each customer's legitimate need for controlled substances. As we identify customers that may be affected by the new threshold-setting methodology, we will work with you and your customers to collect and evaluate information. We are committed to working with our pharmacy customers to help them understand their obligations and to do our part to address the issue of pharmaceutical drug abuse.

QRA's management of thresholds is just one aspect of our anti-diversion efforts. It is imperative that all employees continue to vigilantly look for signs of potential diversion. If you see or hear anything that raises concerns, please contact our compliance hotline at 1-800-926-0834.

**Sincerely,**

**Todd Cameron**

**Vice President, Quality and Regulatory Affairs**